

# Exhibit C

**Disclosure as to Expert Witness Dr. Rajat Deo****I. Statement of Opinions, Bases and Reasons**

Dr. Deo's opinions are based upon his education, personal medical training, research, interactions with patients, interactions with other physicians, and experience in the fields of cardiovascular medicine, clinical genetic testing especially as it pertains to various cardiac disorders, clinical investigation, and scientific methodology. Dr. Deo will help the jury understand the nature and appropriate uses of the tests ordered as part of the charged conspiracy. As part of this testimony, he will highlight the appropriate procedures for implementing a genetic testing program in clinical medicine. Dr. Deo will also help the jury understand the limitations of these tests and the physical and mental risks that patients can incur when these tests are implemented without appropriate indications and counseling. Dr. Deo may also be asked to review laboratory test requisition forms. He will also provide his opinion as to whether the records demonstrate that a particular test was medically reasonable and medically necessary.

***a. Opinions and Summary of Anticipated Testimony***

The government anticipates Dr. Deo's testimony will bear on whether the Cardiovascular Genetic Testing ("comprehensive hereditary cardiac gene panel" or "cardiac genetic testing") ordered in this case was medically necessary and ordered in the absence of a valid practitioner-patient relationship and examination.

- The government anticipates that Dr. Deo's testimony (1) will describe what cardiac genetic testing is, its purpose and use in appropriate cases, how such tests are administered, and distinguish cardiac genetic testing from other forms of genetic testing that are commercially available; (2) will describe clinically appropriate uses of cardiac genetic testing; (3) will explain that cardiac genetic testing should be preceded by a discussion of the risks and benefits to patients and their families; (4) will highlight the accepted use of genetic counselors to complement the cardiologist's role in genetic testing; (5) will provide examples of clinically inappropriate use of cardiac genetic testing and explain how results are used in conjunction with the appropriate practice of medicine and continuing care of patients; (6) will explain the spectrum of possible results, sample reports and how they are interpreted, and how the results are properly used in conjunction with the provision of appropriate medical care; (7) will contrast and distinguish cardiac genetic testing from diagnostic tests used in the practice of medicine to detect the existence of and to treat cardiovascular disease; and (8) will discuss his review and analysis of the manner by which cardiac genetic testing was employed in this case; and (9) explain the significance of the lack of any follow-up or counseling after the genetic testing results had been obtained. Finally, (10) he will explain how genetic testing performed in clinical practice is different than the testing and evaluation that are performed as part of biobanking efforts and research protocols.
- Dr. Deo may answer hypothetical questions based upon the facts of this case and opine whether the cardiac genetic testing described in hypotheticals constituted an appropriate practice of medicine or was medically necessary. Dr. Deo will explain that multiple professional societies including the American College of Medical Genetics, the American Heart Association, the American College of Cardiology, the Heart Rhythm Society, and the European Society of

Cardiology develop guidance regarding the standard for clinical policy in cardiac genetic testing.

- Dr. Deo may also review documents that have been produced to the Defendant and offer opinions on those documents based on his extensive relevant training and experience as described in Dr. Deo's curriculum vitae ("CV"). For example, Dr. Deo may offer opinions on the testing purportedly conducted on specific patients in this case, including opinions regarding whether the testing was medically appropriate, based on his experience and the principles discussed herein. The government anticipates that Dr. Deo will opine that, if no legitimate doctor-patient relationship existed in connection with ordering cardiac genetic testing and the results were not used by the ordering provider to manage the patient, the cardiac genetic testing would not be medically necessary or appropriate.

### **Cardiac Genetic Testing**

- Dr. Deo will explain what cardiac genetic testing is. Commercial testing has evolved tremendously. Cardiac genetic testing evaluates for genetic variations or mutations associated with certain inherited cardiac diseases. As a general matter, it is not appropriate to use these tests as a routine screening tool in the general population. Instead, the tests should be used for a medical decision-making purpose. Thus, it is essential that the tests be ordered by a medical professional who is actually treating the patient and uses the results in the patient's treatment, and a professional who can appropriately counsel the patient about the benefits and risks of these tests.
- In a patient where an inherited cardiac syndrome is suspected, a cardiac genetic test may be indicated as a tool to assist treating physicians, gather information, discuss treatment options and assist patients with making informed decisions about their care. Genetic testing generally complements a comprehensive medical work-up that includes structural phenotyping with electrocardiography, echocardiography, stress testing, cardiac catheterization, cardiac CT scan and cardiac MRI. Cardiac genetic tests should only be ordered to complement a comprehensive care program managed by one or more physicians or appropriately trained health care providers with the expertise to assess such conditions. Managed by a physician treating these patients, the information obtained from cardiac genetic testing can play a meaningful role in providing quality care. It can also assist with cascade screening of family members to identify those at increased risk of having or developing the disease. As such, this process of determining whether a family member is likely to have a gene or mutation associated with an inherited cardiac disease can assist in early treatment or risk management.
- For chronic medical conditions such as essential hypertension and diabetes, especially in the elderly population, cardiac genetic testing is rarely indicated and has the potential to result in emotional harm and anxiety. Very rarely does it result in any beneficial intervention or treatment.
- A primary care physician or other non-specialist physician should not normally order cardiac genetic testing; instead, such testing is typically ordered after referral to a specialist, who has expertise in evaluating and managing inherited conditions. Often, these practitioners will also

have a more extensive infrastructure that includes genetic counselors, who are integral to the medical team throughout the duration of medical care.

- In the absence of cascade screening, cardiac genetic testing is never the first step in managing a patient's cardiac-related illness particularly for a patient with no diagnosed first-degree familial cardiac genetic mutation.
- Dr. Deo may answer hypothetical questions, including hypothetical questions drawn from the facts of this case, to further explain what would be, in his opinion, medically appropriate and inappropriate uses of these tests.
- Dr. Deo may contrast cardiac genetic testing from other forms of tests which are diagnostic in nature designed to identify the presence of cardiac disease, such as for example, electrocardiograms, echocardiograms, stress tests, cardiac catheterization, CT scans, and cardiac MRIs.
- Cardiac genetic testing results are frequently complex and inconclusive in nature such that they require the skills of a properly trained physician or other properly trained and certified health care provider to accurately interpret them in a manner that is useful to the patient. Absent involvement by a competent treating physician, there is unreasonable risk that patients could misinterpret the findings. Further, inconclusive results could also lead practitioners to order other unnecessary tests and procedures, that place the patient at increased risk of complications. Cardiac genetic testing results have the potential to lead practitioners to make premature and unwarranted medical decisions, or conversely to take an apathetic approach to the patient's health based upon a false sense of security. As such, follow-up evaluation and longitudinal testing are often appropriate and necessary to ensure proper care. Information revealed by cardiac genetic testing can also exact psychological tolls on patients absent proper management, including pre- and post- testing genetic counseling, by a trained professional.
- Dr. Deo may explain that cardiac genetic testing results can also be misleading especially when used for population-based screening. For example, a negative result does not mean that a particular patient will not develop cardiac disease, nor does it mean that the patient has a reduced overall risk for the future development of cardiovascular disease in his or her lifetime. Absent comprehensive genetic counseling, a patient could misinterpret a negative test result to their future detriment.
- Dr. Deo may testify that in a limited number of high-risk patients, such as those with a first-degree family member diagnosed with an inherited cardiac disease, the potential benefits of cardiac genetic testing outweigh potential risks and such testing may be medically indicated. Patients having relatives with a vague history of cardiac disease do not qualify as ones suggestive of an inherited cardiac syndrome. Further, some form of cardiac disease is quite common in the general population but does not by itself warrant cardiac genetic testing. In addition, patients with certain unique clinical presentations, such as a very young patient experiencing cardiac arrest, are referred to sub-specialty care and may also warrant cardiac genetic testing.

- Dr. Deo may testify that, when a treating physician decides that it is in his or her patient's best interest to receive cardiac genetic testing and subsequently orders it, the testing should be accompanied by comprehensive pre- and post- testing genetic counseling provided by a genetic counselor, physician, or health care provider with appropriate training and experience in the area of genetic medicine. Genetic counseling is a service provided by a properly credentialed medical provider who helps to explain the purpose of a genetic test, how the test will be performed, what the results will look like, what different results might mean, and what the implications of those results might be in terms of how they might affect treatment. Genetic counseling is also useful to explain to patients what impact, if any, cardiac genetic testing results might have on other immediate family members, especially children.
- Dr. Deo may offer opinions on the testing purportedly conducted on specific patients in this case, including opinions regarding whether testing of specific patients was medically appropriate, based on his experience and the principles discussed herein.

### **Medical Records**

- The Government anticipates that Dr. Deo will testify that, as a treating physician, he is familiar with the importance of thoroughly documenting his patients' medical charts. Dr. Deo will testify that the purpose of a medical chart is to document the patient encounter, record the information reviewed and document a future plan of care for the patient. Proper charting is vital to continued care of patients, because health care providers see patients in episodes over a period of time. When it comes to cardiac genetic testing, patients' medical charts should reflect the provider's bases for ordering the testing, which type of test was employed, and how the decision to conduct genetic testing fits into the referring physician's treatment plan for the patient.

### **Review of Records**

- Dr. Deo has reviewed what appear to be genetic testing orders and related records used to submit claims to Medicare in this case and is expected to testify that the information contained in the orders is insufficient to assess the medical necessity of the prescribed genetic tests.
- Dr. Deo is expected to review that the medical records from providers do not support the use of genetic testing for diagnostic or treatment purposes.
- Dr. Deo is also expected to testify regarding deficiencies in the records that the laboratory obtained and used to support the claims for the genetic tests, including the lack of: (1) intake paperwork establishing a practitioner-patient relationship, (2) an indication as to how the patient was referred to the provider, (3) notes regarding the patient's chief complaint, (4) examination notes, (5) notes documenting the patients' vitals, (6) a treatment plan, (7) a discussion of comorbidities, (8) an explanation as to how the results of the genetic testing will be used in the treatment of the patient, (9) an explanation as to why certain genes were selected for testing, (10) documentation reflecting that the patient was advised of the risks and benefits of such testing and that the patient had the opportunity to ask the prescribing provider questions before undergoing the testing. Dr. Deo would expect the records to include to cover greater specifics in these areas if genetic tests were being legitimately prescribed.

## II. Qualifications

### *a. Qualifications*

In sum, Dr. Dr. Deo holds an SB from the Massachusetts Institute of Technology (MIT), an MD from the University of Michigan Medical School, and a Masters of Science in Translational Research from the University of Pennsylvania Perelman School of Medicine. Currently, Dr. Deo serves as the Director of the Penn Arrhythmia Genetics Program at the University of Pennsylvania, where he has also served as a Cardiologist for the Department of Athletics since 2013. Dr. Deo is board certified in Cardiovascular Diseases and Clinical Cardiac Electrophysiology. He is licensed in Pennsylvania. Dr. Deo has been inducted in the American Society for Clinical Investigation. He is also a member of multiple professional and scientific societies, and has held editorial positions for numerous medical journals and is a reviewer for most major cardiology journals. Dr. Deo has held multiple academic appointments and lectured on cardiology issues multiple times. Dr. Deo has authored hundreds of publications on cardiology, including publications pertaining to cardiac genetic testing. For the past 17 years, he has also received significant funding related to cardiovascular genetics and risk stratification from the National Institutes of Health.

Dr. Deo's CV, which is attached, sets out his qualifications in greater detail.

### *b. Publications*

Dr. Deo has authored several publications in the previous 20 years. A list of these publications is available in Dr. Deo's CV.